

**THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellant(s): Breton, et al.
Appl. No.: 10/505,305
Conf. No.: 6006
Filed: October 27, 2004
Title: ORALLY ADMINISTABLE COMPOSITION FOR THE
PHOTOPROTECTION OF THE SKIN
Art Unit: 1651
Examiner: Irene Marx
Docket No.: 112701-434

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S REPLY BRIEF

Sir:

I. INTRODUCTION

Appellant submits Appellant's Reply Brief in response to the Examiner's Answer dated May 28, 2009 pursuant to 37 C.F.R. § 41.41(a). Appellant respectfully submits that the Examiner's Answer has failed to remedy the deficiencies with respect to the non-final Office Action dated July 24, 2008 as well as the final Office Action dated December 24, 2008, as noted in Appellant's Appeal Brief filed on March 3, 2009, for at least the reasons set forth below. Accordingly, Appellant respectfully requests that the rejections of pending Claims 1-10 and 25-30 be reversed.

II. THE REJECTION OF CLAIMS 1-10 AND 25-30 UNDER 35 U.S.C. §103(A) TO VESELY, RUNGE, BERGGREN, BRASSART AND REDDY SHOULD BE REVERSED BECAUSE THE EXAMINER HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS WITH RESPECT TO THE PENDING CLAIMS

Appellant respectfully requests that the Board reverse the obviousness rejection of Claims 1-10 and 25-30 because the Examiner has still failed to establish that the pending claims are obvious in view of *Vesely* taken with *Runge*, *Berggren*, *Brassart* and *Reddy*. Specifically, Appellant submits that (1) the cited references, alone or in combination, fail to disclose or suggest each element of the pending claims, (2) the skilled artisan would have no reason to combine the cited references because the references are in no way directed to skin photoprotection and, instead, are directed to unrelated compositions utilizing different nutritional ingredients for different objectives, and (3) the Examiner is applying hindsight reconstruction and has failed to set forth sufficient reasons for how the skilled artisan would arrive at the claimed invention in view of the cited references.

1. Contrary to the Examiner's assertion, the claimed composition is sufficiently specific to establish the enhanced effect or response noted in the Affidavit

In the Examiner's Answer, the Examiner asserts that there is nothing specific about the compositions as claimed. See, Examiner's Answer, p. 5, lines 10-12 and p. 7, lines 5-19. Appellant respectfully disagrees and submits that the Affidavit of April 18, 2008 ("*Affidavit*") establishes the enhanced effect or response of the presently claimed composition of probiotic lactic acid bacterium, carotenoids and yeast extract. Specifically, the *Affidavit* describes a study where a composition of the three constituents above provides synergistic effects as compared to compositions lacking the exact combination of constituents. For example, the composition according to the present disclosure having a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract (column 3) showed the greatest immunological response to the dinitrofluorobenzene ("DNFB") allergen applied to the skin. By contrast, the "matrix" formula (i.e. carotenoid and yeast with no probiotic) and the formula with only carotenoids each failed to block or reduce the clinical, histological and

immunological effect of UVR exposure on the skin of the animal. Therefore, it is apparent that each of the three constituents (probiotic lactic acid bacterium, carotenoids and yeast extract) is necessary for providing the photoprotective effects so claimed.

2. Contrary to the Examiner's assertion, one having skill in the art would have no reason to combine *Vesely* with *Reddy*

In the Examiner's Answer, the Examiner also asserts that the cited references are combinable because the compositions of each reference all include at least one probiotic lactic acid bacterium, with *Vesely* containing carotenoids and *Reddy* specifically containing at least one probiotic bacterium and yeast extract. See, Examiner's Answer, p. 5, lines 16-20. Applicants respectfully disagree and submit that, besides being unrelated to skin photoprotection, one skilled in the art would have no reason to replace the B-vitamins in the composition of *Vesely* with the autolyzed yeast extract taught in *Reddy*. As is known by those skilled in the art, yeast extract and particularly the autolyzed yeast extract taught in *Reddy*, is most generally used in products such as Vegemite and Marmite, and as a common source of monosodium glutamate (MSG), a widely used flavor enhancer. The products of *Vesely* having vitamin-B, however, do not refer to any flavor enhancers besides sugars. Instead, vitamin-B is always included as part of a list of vitamins included in each of the respective products. Therefore, based on the disclosure of *Vesely* and *Reddy*, one skilled in the art would have no reason to replace vitamin-B with a well-known flavor enhancer such as autolyzed yeast extract.

3. Contrary to the Examiner's assertion, Appellant's *Affidavit* provides sufficient disclosure to establish a nexus between the claimed invention and results provided

In the Examiner's Answer, the Examiner further asserts that (1) there is no nexus of correlation between the La1 bacteria of the *Affidavit* and invention as claimed directed to any probiotic lactic acid, (2) the *Affidavit* fails to specify the level of carotenoids between 10⁻¹²% to 20% by weight in the composition or the amount of yeast extract, and (3) the *Affidavit* fails to provide the amounts in the "matrix" formula. See, Examiner's Answer, p. 7, line 28 to page 8,

line 8; page 8, lines 16-18 and 23-26, and page 9, lines 5-12. Appellant respectfully disagrees with each of these assertions for the reasons below.

Regarding assertion (1), Appellant submits that the skilled artisan would understand that broadening out the La1 – *Lactobacillus johnsonii* to encompass other probiotics and broadening out lycopene to encompass other carotenoids serves as Appellant's prophetic examples. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved.

In response, the Examiner asserts that these "allegations" of prophetic examples are not persuasive of error in the rejection. Appellant submits, however, that by broadening La1 and lycopene, the contents of the *Affidavit*, including its study and corresponding results, encompass the "probiotic lactic acid bacterium" and "at least one carotenoid" elements of the present claims. Therefore, the teachings of the *Affidavit* further establish the synergistic effects of the claimed combination, which Appellant asserts is lacking in the teachings of the cited art and is persuasive of error in the combining of the prior art to arrive at the present claims.

Regarding assertion (2), Appellant submits that, as established in Appellant's specification, the carotenoid element of the claimed composition may be present in the carrier in an amount of from $10^{-12}\%$ to 20% by weight. See, Appellant's specification (Preliminary Amendment filed August 20, 2004), p. 6, lines 25-27. Moreover, regardless of the carotenoid level in the formulas used in the *Affidavit*, the results clearly show that the formulas having carotenoids and yeast extract ("matrix formula") or carotenoids alone do not sufficiently photoprotect skin like the claimed formula including the synergistic combination of carotenoids, yeast extract, and probiotic lactic acid bacterium. Therefore, the *Affidavit* at least effectively proves the synergistic quality of the combined constituents of the claimed composition, a quality that Appellant asserts above to highlight the deficiencies of the cited references as well as the improper combining of the cited references.

Regarding assertion (3), Appellant respectfully submits that since the present claims do not recite any yeast extract level, the mere presence of the yeast extract in the "matrix" formula is sufficient. Moreover, regarding the carotenoid amount in the "matrix" formula, Appellant again submits that regardless of the carotenoid level in the formulas used in the *Affidavit*, the results clearly show that the formulas having carotenoids and yeast extract ("matrix" formula) or carotenoids alone do not sufficiently photoprotect skin like the claimed formula including the

synergistic combination of carotenoids, yeast extract, and probiotic lactic acid bacterium. Therefore, the *Affidavit* at least effectively proves the synergistic quality of the combined constituents of the claimed composition.

For the above reasons, Appellant respectfully submits that the cited references, alone or in combination, fail to disclose or suggest every element of the present claims. Further, the cited references are not combinable because they are directed toward completely different products with completely different objectives.

Accordingly, for at least the reasons discussed above, Appellant respectfully submits that Claims 1-10 and 25-30 are novel, nonobvious and distinguishable from the cited references and are in condition for allowance.

VIII. CONCLUSION

Appellant submits that the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. §103(a) with respect to the rejection of Claims 1-10 and 25-30. Accordingly, Appellant respectfully submits that the obviousness rejection is erroneous in law, and in fact, and therefore should be reversed by this Board.

The Director is authorized to charge any other fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal occurs, please indicate the Attorney Docket No. 112701-434 on the account statement.

Respectfully submitted,

K&L Gates, LLP

BY 

Robert M. Barrett
Reg. No. 30,142
Customer No. 29157

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